

REMARKS

Claims 1-3,6, 15, 22, 24-27,33, 37-39, 42-43, and 45-56 remain pending after amendment.

Claim Amendments

By this amendment, claim 23 is cancelled and rewritten as new claim 56. No new matter is added by this amendment.

Restriction/Election Requirement

Applicants acknowledge with appreciation the rejoinder of claims 1-3, 6,15, 22-27, 38, 39, 42 and 43 in view of the prior restriction requirement.

Allowable Subject Matter

Applicants thank the Examiner for the indication of allowable subject matter of claims 8, 10, 12-14, 28-30, 32, 33, 36, 37, 40 and 41. However, in view of the rejoinder of previously-withdrawn claims, it is believed that claims 1-3, 6, 15, 38, and 39 are also directed to allowable subject matter and should be so designated.

Objection to Claims

Claim 23 is objected to by the Examiner as being improperly dependent upon claim 33. In response, claim 23 is rewritten as new claim 56. The objection should accordingly be withdrawn.

Rejection under 35 USC 112 (paragraph one)

Claims 22-27, 33 and 46-55 stand rejected under 35 USC 112 (paragraph one) as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In essence, the Examiner appears to focus the rejection upon the use of the term “prophylaxis” of IBD. This rejection respectfully is traversed.

With regard to the “prophylaxis” embodiment, xanthan gum and HPMC are both mucoadhesive polymers which are not metabolized by the body. Hence, these compounds pass through the GI tract unchanged. Both polymers are inert (e.g., they are relatively resistant to micro-organisms) and have a high molecular weight. See page 1, lines 11-19 of the specification in this regard. Both xanthan gum and HPMC contact the gut mucosa and act as a protective layer – e.g., a kind of “dressing” for inflamed mucosa which prevents, in the case of pouchitis, for instance, the deleterious effect of the fecal

stasis of the bile acids and of the micro-organisms which are known to be at the origin of the pouchitis.

Patients with pouchitis (who also have primary sclerosing cholangitis) have a 63% risk of developing chronic pouchitis (Penna C., Dozois, R., Tremaine, W. et al, "Pouchitis after Ileal Pouch-Anal Anastomosis for Ulcerative Colitis Occurs with Increased Frequency in Patients with Associated Primary Sclerosing Cholangitis", *Gut*, 1996, Feb. 38(2),234-239. It would be appropriate to use the enemas of the present invention as a prophylactic in these cases. In addition, patients with recurrent pouchitis who are brought into remission with antibiotics could be treated with a prophylactic therapy such as these enemas. This has recently been shown to be effective therapy using probiotic therapy for prophylaxis of pouchitis. Minura, T., *Gut*, 53: 108-114, 2004.

In view of the above facts, applicants assert that the claimed enemas could be successfully used as prophylactic compositions. One of ordinary skill in the art would readily appreciate and be able to practice the claimed prophylactic method using the recited compositions given available information with the requisite degree of predictability, the fact that the amount of direction provided is minimal, the fact that little if any experimentation is required, and the relatively simple nature of the claimed invention.

In view of the above, it is believed that the rejection is without basis and should be withdrawn.

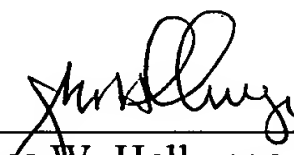
The application is now believed to be in condition for allowance and an early indication of same is earnestly solicited.

In the event that any outstanding matters remain in this application, Applicants request that the Examiner contact James W. Hellwege (Reg. No. 28,808) at (703) 205-8000 to discuss such matters.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Very truly yours,

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